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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,933	01/20/2006	Sascha Kruger	DE030264US1	9385

24737 7590 02/03/2009

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
HOFFA, ANGELA MARIE	
ART UNIT	PAPER NUMBER
3768	
MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,933	KRUGER ET AL.	
	Examiner	Art Unit	
	Angela M. Hoffa	4138	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to communication filed on January 8, 2009 regarding application No. 10/565,933 filed on January 20, 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Publication "Flow Rate Measurement using Ultrasonic Doppler Method with Cavitation Bubbles" to *Koike et al.* and further in view of U.S. Patent Publication No. 2003/0139041 A1 to *LeClair*.

In regards to Claim 1, *Koike et al* discloses a device for measuring flow in a fluid, comprising a cavitation unit ("cavitation bubbles generating system") and a particle-measuring unit ("measurement system"), (Page 2, Paragraph 2, Lines 1-6; Figure 2).

However, *Koike et al* does not disclose wherein the cavitation unit comprises a cavitation light laser source.

However, *LeClair* discloses a method and apparatus for forming cavitation bubbles wherein cavitation bubbles generated via ultrasound or laser light (Par. 0042) are equivalent.

Therefore, because these two cavitation bubble generation methods were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute a laser light cavitation source for an ultrasonic cavitation source.

In regards to Claim 3, *Koike et al* discloses a particle-measuring unit utilizing the Doppler shift ("Ultrasonic pulse Doppler Method", Abstract, Line 3).

In regards to Claim 4, *Koike et al* discloses a particle-measuring unit that detects reflected light from cavitation bubbles (Abstract, Lines 7-9). A unit that is capable of detecting light reflected by the bubbles is capable of detecting light emitted by the bubbles as there is no dependence on the source of the light.

In regards to Claim 13, *Koike et al* discloses a method of measuring fluid flow wherein cavitation bubbles are generated and the movement of the bubbles is observed (Abstract).

However, *Koike et al* does not disclose wherein the cavitation unit comprises a cavitation light laser source.

However, *LeClair* discloses a method and apparatus for forming cavitation bubbles wherein cavitation bubbles generated via ultrasound or laser light (Par. 0042) are equivalent.

Therefore, because these two cavitation bubble generation methods were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute a laser light cavitation source for an ultrasonic cavitation source.

5. Claims 5-9, 11-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Publication "Flow Rate Measurement using Ultrasonic Doppler Method with Cavitation Bubbles" to *Koike et al.* in view of U.S. Patent Publication No. 2003/0139041 A1 to *LeClair* as applied to the claims above and further in view of U.S. Patent Publication No. 2002/0045811 A1 to *Kittrell et al.*

Regarding Claim 5, *Koike et alin view of LeClair* do not disclose a catheter having an optical unit.

However, *Kittrell et al* discloses a facility comprising a catheter with an optical unit that is disposed at the catheter tip that is capable of receiving light selectively from a focus region situated outside the catheter or beam light selectively into the focus region and wherein the radial position of the focus region can be adjusted externally (Abstract, Paragraph 0106, Lines 15-20; Paragraph 0093).

It would have been obvious to one of ordinary skill in the art to focus a region of laser light and adjust the focus region in order to provide additional

functions such as performing spectroscopy or laser treatment as taught by *Kittrell et al* (Abstract).

In regards to Claim 6, *Kittrell et al* further discloses an optical unit that can be rotated around the elongated axis of the catheter relative to the catheter (Paragraph 0093, Lines 5-8).

In regards to Claim 7, *Kittrell et al* further discloses a catheter comprising a bundle of optical waveguides ("coherent bundle", Paragraph 0088).

In regards to Claim 8, *Kittrell et al* further discloses a scanning unit that varies the position of the lasing region (Paragraph 0158, Lines 21-24) based on the analysis of light picked up from the focus region with regard to characteristic properties of the area (Paragraphs 0150; Figure 24).

In regards to Claim 9, *Kittrell et al* further discloses a spectrometer ("spectral analyzer 60", Paragraph 0117).

In regards to Claim 11, *Kittrell et al* further discloses an activation unit ("coupler 46", Paragraph 0068, Lines 1-4) used to inject light into a focus region whereby initiating local processes such as removing lesions or obstructions in a vessel (Paragraph 0158, Lines 1-4).

Regarding Claim 12, *LeClair* further discloses wherein it is common knowledge in the art at the time of invention that cavitation bubbles are the cause of ablation during laser ablation processes (Par. 0006).

Regarding Claim 14, *Koike et al* and *LeClair* do not disclose a method of determining the position of a vessel wall.

Kittrell et al discloses a method for determining the position of a vessel wall using qualitative spectroscopic characteristic changes (Paragraph 0128, Lines 9-10; Paragraph 0127). Methods for continuously displacing the focus region for determining the position of a vessel wall are also disclosed (Paragraphs 0093 and 0102). *Kitrell et al* uses a device as discussed in the rejection for Claim 5 above.

It would have been obvious to one of ordinary skill in the art at the time of invention to use the method taught by *Kittrell et al* to continuously displace the focus region in order to measure the position of a vessel wall because it was known in the art to ultilize a light laser for this purpose as shown by *Kittrell et al.*

6. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Publication "Flow Rate Measurement using Ultrasonic Doppler Method with Cavitation Bubbles" to *Koike et al.* in view of U.S. Patent Publication No. 2003/0139041 A1 to *LeClair* as applied to the claims above in further view of Publication "Measurement of the Velocity of Blood Flow (in vivo) Using a Fiber Optic Catheter and Optical Mixing Spectroscopy" to *Tanaka et al*.

Regarding Claim 5, *Koike et al* in view of *LeClair* do not disclose a catheter having an optical unit.

Tanaka et al discloses a facility comprising a catheter with an optical unit that is disposed at the catheter tip that is capable of receiving light selectively from a focus region situated outside the catheter or beam light selectively into the

focus region and wherein the radial position of the focus region can be adjusted externally (Figure 2; Page 192, Paragraph 3, Lines 24-28).

It would have been obvious to one of ordinary skill in the art at the time of invention to focus and position laser light in order to measure blood flow velocity as taught by *Tanaka et al* (Page 191, Section III, first sentence).

Regarding Claim 10, *Tanaka et al* further discloses a particle measuring unit that measures flow using the Doppler anemometry technique (Figure 2; Page 190, Paragraph 2).

Response to Arguments

7. Applicant's arguments, see Page 2, first paragraph, filed January 8, 2009, with respect to the rejection(s) of claim(s) 4 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive with the amendment to the claim. Therefore, the rejection has been withdrawn.

8. Applicant's arguments, see Page 2, 4th paragraph, filed January 8, 2009, with respect to the rejection(s) of claim(s) 1-4 and 13 under 35 U.S.C. 102(b) have been fully considered and are persuasive with the amendment to the claims. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference showing equivalence of producing cavitation bubbles from laser or ultrasonic sources.

9. Applicant's arguments, see Page 3, first paragraph, filed January 8, 2009, with respect to the rejection(s) of claim(s) 5-9, 11 and 14 under 35 U.S.C. 102(b) have been fully considered and are persuasive with the amendment to the claims. Therefore, the

rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of combining references based on the amendment to combine claim limitations.

10. Applicant's arguments, see Page 3, 4th paragraph, filed January 8, 2009, with respect to the rejection(s) of claim(s) 5 and 10 under 35 U.S.C. 102(b) have been fully considered and are persuasive given the amendment to the claims. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of combining references based on the amendment to combine claim limitations.

11. Applicant's arguments, see Page 3, paragraph 6, filed January 8, 2009, with respect to the rejection(s) of claim(s) 12 under 35 U.S.C. 103(a) have been fully considered and are persuasive given the amendment to the claims. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a new combination of prior art references to reflect the changes of combining claim limitations. The new prior art reference discloses equivalence of producing cavitation bubbles from laser or ultrasonic sources and wherein cavitation is commonly known in the art as the destruction means in laser ablation within blood vessels.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Hoffa whose telephone number is 571-270-7408. The examiner can normally be reached on Monday - Friday, 7:30 am - 5:00 pm with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on 571-272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melba Bumgarner/
Supervisory Patent Examiner
Art Unit 4138

/A. M. H./
Examiner, Art Unit 4138